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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,586	03/17/2006	Masakazu Takeuchi	082368-004500US	9187

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EXAMINER	
CHERNYSHEV, OLGA N	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,586	TAKEUCHI ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8 and 10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/4/8*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 07, 2008 has been entered.

Response to Amendment

2. Claims 1, 5, 7, 10 and 12 have been amended and claims 14-15 have been added as requested in the amendment filed on January 30, 2008. Following the amendment, claims 1-5, 7, 8 and 10-15 are pending in the instant application.

Claims 1-5, 7, 8 and 10-15 are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on August 07, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2, 3, 5, 7, 8 and 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 5 and 7 are vague and ambiguous for recitation of a fragment which "comprises at least eight amino acid residues and a PET (Prickle Espinas Testin) domain". The metes and bounds of the claimed subject matter cannot be determined from the claims or the instant specification. Specifically, the specification (and claims 13-15) defines PET domain as the amino acid sequence of residues 19-89 of SEQ ID NO: 1. Thus, it appears that the claimed molecules of claims 5 and 7 must be limited by the polypeptide fragment 19-89 of SEQ ID NO: 1 and eight amino acids on one or either end of the fragment. This is not, however, what is claimed because it is not clear if the recited eight amino acids belong to any particular known structure, or if they are randomly selected and added to the total "at least" eight count to both ends. Because the structure of the claimed molecular embodiments is not clearly defined, a skilled artisan cannot determine if, for example, a fragment with two amino acid residues that precede the residue 19 of SEQ ID NO: 1 and six random amino acids that follow the residue 89 of SEQ ID NO: 1 would be then included or excluded by the presence of the limitation. Applicant is advised to revise the language of the claims to better present the claimed subject matter to avoid the ambiguity in the claim interpretation.

7. Further, claims 5, 7 and 12 recite "PET domain" and "LIM domain" as limitations. Since these domains are not known in the art to be associated with a specific structure and further because the domains are further defined in claims 13-15 by reference to the

specific amino acid sequences, it is suggested for claims 5, 7 and 12 to include references to the sequence identifier (such as in claims 13-15) to clearly identify the PET and LIM domains.

8. Claim 10 is vague and indefinite for reciting two polynucleotides in the preamble, which leads to the lack of antecedent basis for "the polynucleotide" within the claim. Specifically, claim 10, as currently presented, encompasses polynucleotides of complementary strand and specifically requires the polynucleotide to encode a polypeptide, which does not make sense.

9. Claim 2, 3, 8, 11 and 13-15 are indefinite for being dependent from indefinite claims.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 1-5, 7, 8 and 10-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility for reasons of record in section 7 of Paper mailed on August 30, 2007 and in section 12 of Paper mailed on April 10, 2008.

Applicant traverses the rejection by submitting Declaration of Dr. Masakazu Takeuchi under 37 CFR 1.132 (discussion of the declaration at pp. 8-9 of the Response). Applicant's arguments are fully considered and answered below within the response to the Declaration.

The Declaration of Dr. Masakazu Takeuchi under 37 CFR 1.132 filed on August 07, 2008 is insufficient to overcome the rejection of claims 1-5, 7, 8 and 10-15 based upon 35 U.S.C 101/112, first paragraph as set forth in the last Office actions for the following reasons.

The Declaration provides the following lines of reasoning to support the utility of the claimed molecules:

1. Because the rat Prickle protein was found to be concentrated in PSD (postsynaptic density) fraction, it contributes to memory function (see section 5 of the Declaration, "At the time of the invention, a skilled artisan would readily conclude that proteins associated with the PSD contribute to memory formation. Notably, the inventors have determined that the m-Prickle protein is concentrated in the PSD fraction (see Example 6, and Figure 5 of the specification). Thus, based on this observation, one of skill would conclude that the m-Prickle protein contributes to memory formation"). This argument has been fully considered but is not persuasive because one readily appreciates that postsynaptic density fraction contains plurality of proteins, not all of them directly contributing to the memory function. The Kennedy reference fails to support Declarant's assertion that any protein within the PSD fraction can be immediately identified as directly associated with memory function.

2. Because PSD-95 plays role in learning and the instant Prickle protein is shown to bind to PSD-95 via LIM domain, then the claimed protein plays a role in learning and memory (see sections 6 and 7 of the declaration, " it was also known that PSD-95 at synapses plays a functional role in learning and memory by interacting with other signal molecules. [...] The present invention also shows that the m-Prickle protein possesses LIM domains, which are known to function as protein interaction domains, mediating specific contacts between members

of functional complexes and modulating the activity of constituent proteins. [...] Based on this observation, one of skill would recognize that the m-Prickle protein plays a role in learning and memory by interacting with PSD-95 via its LIM domains"). These arguments have been given already considered and answered in the previous office action of record, see section 12 of Paper mailed on April 10, 2008. Briefly, the ability of the instant rat protein of SEQ ID NO: 1 to bind other proteins because of the presence of LIM and PET domains in its structure does not support the immediate role of the claimed molecules as targets "for screening compounds that affect learning and memory" (section 9 of the Declaration). The instant specification asserts a role for the claimed molecules in physiological processes associated with learning and memory but fails to reveal this specific role. The Examiner maintains that in the absence of knowledge of the biological significance of this specific nucleic acid of SEQ ID NO: 2 and the encoded protein of SEQ ID NO: 1, the instant claimed molecules are only suitable as objects of further research.

At p. 3, the instant specification states that "mPrickle is expected to be applicable for the diagnosis of learning- and memory-related disorders such as mental deterioration and dementia in the future"; however, the specification provides no evidence that the instant nucleic acid or encoded protein are associated with any disease or disorder, including learning and memory pathologies. Thus, the specification discloses structure of the rat Prickle polypeptides and encoding nucleic acids but provides no meaningful information regarding how to use the Prickle polypeptides and polynucleotides in any specific and substantial way to achieve the stated purpose of clinical and diagnostic utilities. The abstract of the specification states that, "in the future, mPrickle is expected to be applicable to the diagnosis and/or treatment of neurodegenerative diseases associated with learning/memory, such as mental deterioration and

dementia"; however, the Supreme Court desision in *Brenner v. Manson* specifically prohibits patenting future discoveries. The court stated that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695 (cited also in the previous office action of record).

For reasons of record fully explained earlier and reasons above, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-5, 7, 8 and 10-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

14. Claims 1-5, 7, 8 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5, 7, 8 and 10-15 are directed to mammalian Prickle polypeptides and polynucleotides and molecules that are fragments or have limited structural similarity to the mammalian Prickle polypeptides and polynucleotides (95% and 99% identity). The claims do not require that the claimed mammalian molecules possess any particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to genera of mammalian polypeptides and polynucleotides that are defined only by sequence identity to the only described rat polypeptides and polynucleotides. However, the instant specification fails to describe the entire genera of molecules, which are encompassed by these claims.

The instant specification discloses the structure of a rat Prickle protein of SEQ ID NO: 1 encoded by the nucleic acid molecules of SEQ ID NO: 2. Thus, it is clear that Applicant has possession of these two molecules. The claims, however, are drawn to mammalian proteins and polynucleotides and the instant specification fails to describe the entire genus of the claimed molecules. The instant situation is directly analogous to the one described in *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483, where the claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class because the specification provided only the bovine sequence.

Further, the claimed subject matter encompasses fragments of mammalian polynucleotides and polypeptides, however, the specification only describes full length rat sequences. Because the instant specification fails to identify the structural characteristics of mammalian polypeptides that bind PSD-95, a skilled artisan cannot envision the claimed genera of proteins and polynucleotides that bear 95% or 99% structural similarity to the instant described SEQ ID NO: 1 or 2, or fragments thereof and are of mammalian origin.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a reference to partial structure in the form of a recitation of percent identity and to mammalian origin without identification of at least one distinguishing feature of the claimed genera.

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. EliLilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997 (bracketed material in original). The claims in *Lilly* were directed generically to vertebrate or mammalian insulin cDNAs. See id. at 1567, 43 USPQ2d at 1405. The court held that a structural description of a rat cDNA was not an adequate description of these broader classes of cDNAs. The *Lilly* court explained that

> a generic statement such as... 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. at 1568, 43 USPQ2d at 1406. Finally, the *Lilly* court set out exemplary ways in which a genus of cDNAs could be described:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id. at 1569.

Revisited the issue of describing DNA, the court in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002) held that a claimed DNA could be described without, necessarily, disclosing its structure. The court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics.., i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" *See Id.* at 1324, 63 USPQ2d at 1613.

In the instant case, there is no disclosure of sufficiently detailed, relevant identifying characteristics, such as other physical and/or chemical properties, or functional characteristics, that when coupled with a known or disclosed correlation between function and structure (i.e., the sequence), or some combination of such characteristics, would constitute an adequate written description of the claimed invention. All that is disclosed is one rat amino acid sequence and the encoding nucleic acid sequence and identification of certain binding domains not responsible for the asserted utility. While the skilled artisan may be able to determine polypeptides that have

95% and 99% sequence identity with SEQ ID NO: 1, without any disclosure of "mammalian features" or what residues are required for the polypeptide to function as a "target for screening compounds that affect learning and memory" (Declaration of August 08, 2008), the skilled artisan cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus that would be useful for these asserted purposes. Thus, claims 1-5, 7, 8 and 10-15 fail to meet the requirement of written description under 35 U.S.C. 112, first paragraph.

Conclusion

15. No clam is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Olga N. Chernyshev, Ph.D./
Primary Examiner, Art Unit 1649